

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division



LIFENET HEALTH,

Plaintiff,

v.

Civil Action No. 2:13cv486

****Public Version****

LIFECCELL CORPORATION,

Defendant.

OPINION AND ORDER

This matter came before the Court on the numerous Motions in Limine filed by Plaintiff LifeNet Health ("Plaintiff" or "LifeNet") and Defendant LifeCell Corp. ("Defendant" or "LifeCell"). Docs. 220, 226, 228, 230, 232, 234, 237, 240, 243. 283. A hearing was held on October 22, 2014. The Court ruled from the bench, and now issues this Opinion and Order further explaining its reasoning.

1. BACKGROUND

A more complete account of the facts and procedural background of this case can be found in the Court's Opinion and Order denying the parties cross-motions for summary judgment. Doc. 298.

On October 6, 2014, the Court entered an agreed Order setting forth a briefing schedule for motions in limine in this case. Doc. 212. The motions in limine were filed on October 7, 2014. Briefs in opposition were filed on October 17, 2014.

A two-week jury trial in this case is scheduled to commence on November 3, 2014.

2. LEGAL STANDARD

The Federal Rules of Evidence broadly allows for relevant evidence to be admitted, subject

to certain exceptions. Fed. R. Evid. 402. "Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Id. 401. However, relevant evidence may be excluded by the Court if "its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Id. 403.

Additionally, the standards governing the admissibility of expert testimony are well-established. Under Federal Rule of Evidence 702, a qualified expert may present opinion testimony if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "Put another way, a trial judge faced with a proffer of expert scientific or technical testimony must determine 'whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.'" United States v. Fultz, __ F. Supp. 2d __, 2014 WL 1870785, at *5 (E.D. Va. May 9, 2014) (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592 (1993)). This requires the court to assess "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592–93. The trial court has broad discretion in determining how to resolve a Daubert challenge. Fultz, 2014 WL 1870785, at *5 (citing United States v. Beasley, 495 F.3d 142, 150 (4th Cir. 2007)); see also Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1360 (Fed.

Cir. 2008).

The Supreme Court identified four factors to assist judges in undertaking this assessment, although these factors are neither exhaustive nor definitive. Daubert, 509 U.S. at 593. "In evaluating the reliability of expert opinion evidence, a court should consider: (1) whether the theory or technique used by the expert can, and has been tested; (2) 'whether the theory or technique has been subjected to peer review and publication;' (3) 'the known or potential rate of error' of the technique or method used; and (4) the degree of the method's or conclusion's general acceptance within the relevant scientific community." Fultz, 2014 WL 1870785, at *5 (quoting Daubert, 509 U.S. at 593–94). "The proponent of the evidence bears a significant burden in proving reliability; a proffer of expert testimony must include the substantive area of the proposed testimony, as well as sufficient information regarding the bases for the expert's opinion." Fultz, 2014 WL 1870785, at *5 (quoting United States v. Lester, 234 F. Supp. 2d 595, 598 (E.D. Va. 2002) (internal quotation marks and citation omitted)). "'Where the proponent of the testimony fails to present enough evidence to demonstrate to the court the scientific validity of the research supporting the expert's conclusions, the trial court cannot determine whether the testimony is well-founded.'" Fultz, 2014 WL 1870785, at *5 (quoting Lester, 234 F. Supp. 2d at 598).

3. DISCUSSION

A. Defendant's Motion to Exclude Mark Gallagher, Plaintiff's Damages Expert, Doc. 220, and Defendant's Motion in Limine #7 to Exclude the NERA Report and MTF Jury Verdict and Settlement Agreement

Defendant moved to exclude the testimony of Plaintiff's damages expert Mark Gallagher, challenging the basic assumptions underlying Mr. Gallagher's report, his method of calculating damages, and certain materials he relied on in forming his opinions.

In Mr. Gallagher's opening report submitted on August 4, 2014, Mr. Gallagher proposed a

running royalty of [REDACTED] of total accused product revenue. Doc. 251-1 at 4, 251-2 at 6. This amounts to a total royalty of [REDACTED]. Doc. 251-1 at 4. No lost profits were calculated, because Plaintiff does not have the capacity to make all of the sales Defendant can, and is thus not eligible to claim lost profits. Doc. 251-2 at 14.

The first basis for this [REDACTED] figure is an opening offer that Plaintiff extended to Edwards Lifesciences ("Edwards"), in which it offered a one-time lump sum payment of \$7.2 million plus a 5% running royalty payment on net sales. Id. at 19. Plaintiff and Edwards were not competitors, the proposed agreement included rights under multiple patents, and the proposed agreement was in an area Plaintiff did not operate, nor intended to operate. Id. Mr. Gallagher then increased the [REDACTED] figure by [REDACTED] because Plaintiff and Defendant are competitors, Plaintiff operates or intended to operate in the market, and the patented technology provided cost savings. Id. at 29.

On September 19, 2014, Mr. Gallagher submitted a rebuttal report. Doc. 251-1 at 4. In his rebuttal report, Mr. Gallagher admitted that based on new information, his initial assumption of cost savings was too high. Doc. 251-4 at 35. Accordingly, he reduced his overall royalty rate to between [REDACTED] of net revenues, creating a range of [REDACTED]. Id. Moreover, his rebuttal report included an additional basis for his royalty award: a settlement after litigation with the Musculoskeletal Transplant Foundation ("MTF"), in which the parties reached a 5.6% royalty rate after the jury awarded a 6% rate after a verdict involving Plaintiff's Allowash technology. Id. at 14. Defendant states it did not receive this settlement document until well after it received Mr. Gallagher's initial report. Doc. 251-1 at 20. Additionally, at his deposition, Mr. Gallagher identified a report by the consulting group NERA as additional support for the 5% royalty calculation, but the report was not produced by Plaintiff as it is asserting the attorney-client privilege. However, Mr. Gallagher did speak with Mr. Wilson, a LifeNet executive, regarding the

5% royalty figure.

Defendant offered four reasons why this Court should exclude all or part of Mr. Gallagher's opinions. First, it argued that the 5% royalty rate is not based on a reliable foundation, as it relies only on the Edwards offer. Doc. 251-1 at 1. Second, it argued that the [REDACTED] adjustment to this royalty rate has no factual support, and is thus arbitrary. *Id.* at 2. Third, it argued that using total sales revenue is improper in this case, as this case is not one where the Federal Circuit has approved the use of the Entire Market Value Rule ("EMVR"). *Id.* Finally, it asked that the Court exclude all references to the MTF settlement and jury verdict by either Mr. Gallagher or any of Plaintiff's witnesses because it should have been produced earlier and has no probative value in this case. *Id.* at 3. Additionally, it asked that all references to the NERA report be excluded.

After hearing argument from the parties, the Court **DENIED** the Motion as to the 5% royalty rate, as the Edwards offer does have probative value. *See Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 29–30 (Fed. Cir. 2012) (noting the probative value of proposed licenses, but cautioning that such value may be limited). The Court **RESERVED RULING** on the [REDACTED] increase to the base royalty rate included in Mr. Gallagher's opinion, instructing Plaintiff to provide notice to the Court prior to calling Mr. Gallagher, and providing a more detailed explanation for the basis of the proposed [REDACTED] increase to the royalty rate. The Court also **RESERVED RULING** on the applicability of the EMVR. The Court **GRANTED** the Motion in Part as to the MTF settlement and jury verdict. The MTF settlement may come in as rebuttal evidence; however, Plaintiff may not state that the MTF jury verdict was in its favor, but Defendant may bring this fact to the jury's attention if it so chooses. Finally, the Court **RESERVED RULING** on the admissibility of the NERA report.

B. Plaintiff's Motion in Limine #1, excluding the two-minute rinse defense, Doc. 226

Plaintiff moved the Court to exclude Defendant's two-minute rinse defense. As the Court explained in its Opinion and Order denying the motions for summary judgment, the defense is relevant in this case because of the claim language. See Doc. 298 at 11–13. Accordingly, the Court **DENIED** this Motion.

C. Plaintiff's Motion in Limine #2, excluding prior art references that do not pre-date the invention in the '200 patent, Doc. 228

Plaintiff moved the Court to exclude prior art references that do not pre-date the conception date of the '200 patent, arguing that the conception date is March 4, 1998. Defendant argued that the evidence Plaintiff provided addressed bone grafts, not soft tissue grafts, and furthermore did not sufficiently establish the necessary diligence.

"Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice." Spansion, Inc. v. Int'l Trade Com'n, 629 F.3d 1331, 1356 (Fed. Cir. 2010) (quoting Singh v. Brake, 317 F.3d 1334, 1340 (Fed Cir. 2003)). "An idea is sufficiently definite for conception 'when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.'" Spansion, Inc., 629 F.3d at 1356 (quoting Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed Cir. 1994)). The idea need not be perfect: "conception is complete when 'the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.'" Spansion, Inc., 629 F.3d at 1356 (quoting Burroughs Wellcome Co., 40 F.3d at 1228). While the inventor's oral testimony is relevant, it "must be corroborated by 'evidence which shows that the inventor disclosed to others his completed thought expressed in

such clear terms as to enable those skilled in the art to make the invention." Spansion, Inc., 629 F.3d at 1356 (quoting Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985)). Conception is a question of law, based on factual findings. Spansion, Inc., 629 F.3d at 1356. The Federal Circuit has held that to remove a patent as a prior art reference, the inventor must prove either (1) a conception and reduction to practice before the filing date of the prior art reference or (2) a conception date prior to the filing date of the prior art reference combined with diligence and reduction to practice after that date. Taurus IP, LLC v. DaimlerChrysler Corp., 726 F.3d 1306, 1323 (Fed. Cir. 2013). Diligence requires the party to "account for the entire period during which diligence is required." Gould v. Schawlow, 363 F.2d 908, 919 (C.C.P.A. 1966).

The parties contest the factual allegations concerning the date of conception, as many of Plaintiff's exhibits in support of its motion referenced bone grafts. Moreover, Defendant asserted that Plaintiff's evidence does not establish the necessary diligence as required by the Federal Circuit. Without knowing all of the facts, the Court did not have enough evidence to rule at the hearing. Accordingly, the Court **RESERVED RULING** on Plaintiff's Motion in Limine #2.

D. Plaintiff's Motion in Limine #3, excluding the expert testimony of Drs. Erdmann and Duda on the issues of non-infringement and secondary considerations of non-obviousness, Doc. 230

Plaintiff sought the exclusion of Drs. Erdmann and Duda from providing expert testimony as to the issues of non-infringement and secondary considerations of non-obviousness, arguing that their testimony does not meet the requirements of Federal Rule of Evidence 702 and Daubert. Defendant argued that these two surgeons have probative evidence that will assist the trier of fact, based on their personal knowledge and experience.

After reviewing the parties' submissions, and hearing argument, the Court **RESERVED RULING** on this Motion, as the probative value and admissibility under Daubert are unclear at

this time.¹

E. Plaintiff's Motion in Limine #4, Doc. 232, and Defendant's Motion in Limine #5, to exclude expert opinions as to willfulness

Both parties sought the exclusion of each other's expert witnesses on the issue of willful infringement. Defendant focused on Plaintiff's expert's opinion that Defendant could have discovered the '200 patent through a due diligence analysis, and that expert testimony is inappropriate on this issue. Plaintiff contested the credentials of Defendant's proposed expert on this issue.

Courts have allowed expert testimony as to willful infringement, but have noted concerns that such testimony may impermissibly encroach on the function of the Court and the jury. See, e.g., Tyco Healthcare Group, LP v. Applied Medical Resources Corp., No. 9:06cv151, 2009 WL 5842063, at *3–4 (E.D. Tex. Mar. 30, 2009) (allowing an expert to testify as to whether defendant should have sought a legal opinion, but not allowing him to testify as to whether he thought defendant had actual knowledge of the patent-in-suit based on deposition testimony); Oxford Gene Tech, Ltd. v. Mergen Ltd., 345 F. Supp. 2d 431, 443 (D. Del. 2004) (allowing an attorney with eighteen years of experience to testify about the steps a reasonable corporation would take when confronted with an allegation of infringement, but not allowing her to testify "as to the legal standard for willfulness" or whether the defendant's behavior "met the standard of reasonableness.").

Moreover, Congress recently passed the Leahy-Smith America Invents Act, which states in pertinent part that

The failure of an infringer to obtain the advice of counsel with respect to any

¹ Just as the Court cautioned Plaintiff it should not reference willful infringement in its opening statement, the Court cautioned Defendant about referencing the surgeons' proposed testimony in its opening statement.

allegedly infringed patent, or the failure of the infringer to present such advice to the court or jury, may not be used to prove that the accused infringer willfully infringed the patent or that the infringer intended to induce infringement of the patent.

35 U.S.C. § 298. As this was recently enacted, there is little case law interpreting the precise scope of the statute. Plaintiff argues it merely codifies the law of Seagate, which held that there was no affirmative duty to obtain the advice of counsel. In re Seagate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007). Post-Seagate, the Federal Circuit did, however, allow evidence of the failure to obtain the advice of counsel to be considered a factor under the totality of the circumstances in assessing willfulness. Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 698–99 (Fed. Cir. 2008). The legislative history specifically states that Congress intended to abrogate Broadcom. H.R. Rep. No. 112-98(I), 2011 WL 2150541, at *53.

One court has held that the statute's protections "dissolves in the event defendants 'open the door' by attempting to refute a claim of willful infringement by implying that they relied on the advice of counsel." Ultratec, Inc. v. Sorenson Commc'ns, Inc., No. 13cv346, 2014 WL 4976596, at *2 (W.D. Wis. Oct. 3, 2014). Additionally, the statute is silent as to whether the Court may consider an opinion of counsel as to the amount it increases damages should the jury return a finding of willful infringement. Thus, it was unclear at the hearing the precise extent to which the expert's testimony would touch upon, and whether the testimony would run afoul of 35 U.S.C. § 298.

Accordingly, the Court **RESERVED RULING** on these Motions until trial.

F. Plaintiff's Motion in Limine #5, excluding the testimony and testing of Dr. Lee, Doc. 234

Plaintiff sought to exclude the testimony and testing of Dr. Lee, which Defendant intends to argue shows that plasticizers are removed from Defendant's accused products. Because

Plaintiff's concerns went to the credibility and not the admissibility of the testimony, the Court **DENIED** the Motion.

G. Plaintiff's Motion in Limine #6, excluding testimony and opinions concerning non-infringing alternatives, Doc. 237

Plaintiff moved the Court to exclude testimony and opinions offered by Defendant's expert Dr. Badylak as to non-infringing alternatives. However, because Defendant's expert had a sufficient basis for his opinions, and Plaintiff's concerns went to the credibility of the evidence, the Court **DENIED** the Motion.

H. Plaintiff's Motion in Limine #7, excluding testimony of Defendant's damages expert regarding the attributes of the '200 patent

Plaintiff sought to exclude Defendant's damages expert from offering his opinions on the attributes of the '200 patent. However, Defendant's expert is not offering a technical opinion, but rather is offering an opinion as to market alternatives, which necessarily entails some comparison between different products. Accordingly, the Court **DENIED** the Motion.

I. Defendant's Motion in Limine #1, excluding arguments contrary to the Court's claim construction

Defendant sought to exclude four areas of argument it believed that Plaintiff will introduce at trial that runs afoul of the Court's claim construction order: (1) expert testimony from Dr. Kaplan that the "not removed" limitation is met if no plasticizers are removed prior to packaging as opposed to transplantation; (2) testimony or argument that the "not removed" limitation is met only if it is not "necessary" to remove the plasticizers; (3) testimony or argument that some types of plasticizer may be removed and still satisfy the "not removed" limitation; and (4) that room temperature storage is a requirement or feature of the asserted grafts. The Federal Circuit is clear that "[n]o party may contradict the court's claim construction to a jury." Exergen Corp. v.

Wal-Mart Stores, Inc., 575 F.3d 1312, 1321 (Fed. Cir. 2009).

The Court **GRANTED** this Motion in Part. In its Opinion and Order denying the motions for summary judgment, the Court made clear that Plaintiff cannot argue that prior to transplantation actually means prior to packaging. Doc. 298 at 10–11. Additionally, while Plaintiff may not argue there can be deliberate removal of plasticizers from the internal matrix of the accused grafts prior to transplantation, Plaintiff may offer testimony that the plasticizers removed do not come from the internal matrix. Moreover, Plaintiff may offer testimony that part of the plasticizer escapes during formulation or transplantation, which would not constitute removal under the Court's claim construction. Finally, while Plaintiff may not offer testimony that room temperature storage shows that the grafts meet the claim limitation, it may offer evidence that room temperature storage is a feature and benefit of the claimed invention.

J. Defendant's Motion in Limine #2, precluding Plaintiff from arguing that surgeons don't rinse the grafts according to the instructions

Defendant moved the Court to exclude Dr. Qin from testifying that surgeons don't follow the instructions for use with the accused grafts, which call for a two-minute rinse prior to transplantation. Defendant argued, however, that she cannot substantiate her opinions. Plaintiff argued that her observations, while not directly tied to Defendant's products, are instructive of what typically occurs in the operating room.

This Motion is closely linked to Plaintiff's Motion in Limine #3, which seeks the exclusion of Drs. Duda and Erdmann. The Court **GRANTED** this Motion in Part, finding that this evidence may properly be considered rebuttal evidence, and that Dr. Qin's testimony as to her observations regarding surgeons following instructions may not be introduced in Plaintiff's case-in-chief. However, the Court **RESERVED RULING** as to whether Dr. Qin's testimony can come in on

rebuttal, as the Court must first rule on the admissibility of Drs. Duda and Erdmann's testimony, as well as hear the scope of their testimony before ruling on the admissibility of Dr. Qin's testimony.

K. Defendant's Motion in Limine #3, precluding Plaintiff from offering testimony that its products practice the claims of the '200 patent

Defendant moved to exclude testimony from Plaintiff that Plaintiff's own products practice the claims of the '200 patent, because Plaintiff's expert did not conduct any testing on the products. Plaintiff countered that it provided documentary evidence for Plaintiff's expert to review, and that his report contains a 66-page chart showing how Plaintiff's products practice the claims of the '200 patent.

The Court **DENIED** this Motion. Plaintiff's documentary evidence provides a sufficient basis for Plaintiff's expert to opine on this issue, and Defendant's concerns regarding the lack of testing goes to the credibility of the testimony, and not its admissibility.

L. Defendant's Motion in Limine #4, striking Dr. Kaplan's Supplemental Report of October 1, 2014 and to preclude testimony on the referenced documents and/or theories

Defendant moved to strike the Supplemental Report of Plaintiff's expert Dr. Kaplan, who produced an untimely expert report. The report contained no new theories, but listed an additional ten documents that support Dr. Kaplan's opinion that Defendant's accused products are "plasticized soft tissue grafts." However, these documents were produced during the normal course of discovery.

While Federal Rule of Civil Procedure 26 allows a party to supplement its previous submissions, it "does not permit a party to make an end-around the normal timetable for conducting discovery." Colony Apartments v. Abacus Project Mgmt., Inc., 197 F. App'x 217, 223 (4th Cir. 2006). Thus, courts distinguish between "true" supplementation, in which a party is correcting inadvertent errors, as opposed to gamesmanship, in which parties seek to "supplement"

with a "new and improved expert report." Gallagher v. S. Source Packaging, LLC, 568 F. Supp. 2d 624, 630–31 (E.D.N.C. 2008) (internal quotation marks and citations omitted). In considering whether to exclude untimely expert disclosures, this Court considers:

(1) The surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure that surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence.

East West, LLC v. Rahman, No. 1:11cv1380, 2012 WL 4105129, at *5 (E.D. Va. Sept. 27, 2012) (quoting States Rack & Fixture, Inc. v. Sherwin-Williams Co., 318 F.3d 592, 597 (4th Cir. 2003)).

In this case, the documents were previously disclosed during the course of discovery. Additionally, they were not used to form new opinions. Thus, exclusion is too drastic a remedy. Accordingly, the Court **DENIED** the Motion.

M. Defendant's Motion in Limine #6, excluding testimony from Plaintiff's employees inconsistent with the testimony of Plaintiff's Rule 30(b)(6) designees

Defendant moved the Court to exclude testimony from Plaintiff's employees that would contradict deposition testimony of Plaintiff's Rule 30(b)(6) designees. Plaintiff argued, however, that Defendant's topics for the depositions were confusing, that Defendant actually received the testimony from other witnesses, and that cross-examination is an effective remedy should there be any inconsistencies between the deposition testimony and testimony at trial.

Under Federal Rule of Civil Procedure 30(b)(6), a "corporation must make a good-faith effort to designate people with knowledge of the matter sought by the opposing party and to adequately prepare its representatives so that they may give complete, knowledgeable, and nonvasive answers in deposition." Humanscale Corp. v. CompX Intern., Inc., No. 3:09cv86, 2009 WL 5091648, at *1 (E.D. Va. Dec. 24, 2009). "If the persons designated by the corporation do not possess personal knowledge of the matters set out in the deposition notice, the corporation

is obligated to prepare the designees so that they may give knowledgeable and binding answers for the corporation." *Id.* at *2 (quoting United States v. Taylor, 166 F.R.D. 356, 361–62 (M.D.N.C. 1996)). "Federal courts have interpreted this rule as prohibiting a 30(b)(6) representative from disclaiming the corporation's knowledge of a subject at the deposition and later introducing evidence on that subject," unless the corporation "can prove that the information was not known or was inaccessible[.]" Super Future Equities, Inc. v. Wells Fargo Bank Minnesota, N.A., No. 3:06cv271, 2007 WL 4410370, at *8 (N.D. Tex. Dec. 14, 2007) (internal quotation marks and citation omitted).

Here, it appears that Plaintiff's witnesses were able to provide testimony on the disputed subject matters, although it may have come in through a different designee or fact witness. Thus, this is not a situation where Plaintiff was seeking to stymie Defendant from receiving the discovery it was due. Accordingly, the Court **DENIED** the Motion.

N. Defendant's Motion in Limine #7, excluding certain damages-related evidence not timely produced during discovery

This motion was connected with Defendant's motion to exclude Mr. Gallagher's report and testimony. For the reasons stated in Section 3(A), the Court **GRANTED** this Motion in part.

O. Defendant's Motion in Limine #8, excluding references to [REDACTED] and [REDACTED]

Defendant moved the Court to exclude references to [REDACTED] and [REDACTED] arguing that the FDA safe harbor, 35 U.S.C. § 271(e)(1), applies to [REDACTED] and that numerous witnesses for Defendant will testify that [REDACTED] is not an actual product. Although Plaintiff is not seeking damages from the two products, Plaintiff argues that these products exist, that one of Defendant's customers wants Defendant to produce a [REDACTED] product, and if these products are found to infringe the method claims of the '200 patent, they would be subject

to a reasonable royalty if and when they are released.

Whether the FDA safe harbor applies is a question of fact. Eli Lilly and Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir. 1989). Additionally, the parties' arguments as to these two products will become clearer once the evidence is developed at trial. Thus, the Court **RESERVED RULING** on this issue.

P. Motion to Seal the Hearing, Doc. 283

Defendant moved to seal the summary judgment hearing and final pre-trial conference, to protect against the disclosure of trade secrets and confidential information. Plaintiff opposed the motion.

Before this Court may seal court filings, it must: "(1) provide public notice of the request to seal and allow interested parties a reasonable opportunity to object, (2) consider less drastic alternatives ..., and (3) provide specific reasons and factual findings supporting its decision to seal ... and for rejecting the alternatives." Ashcraft v. Conoco, Inc., 218 F.3d 288, 302 (4th Cir. 2000) (internal citations omitted).

In this case, less drastic alternatives existed. Any documents that required the disclosure of trade secrets could be submitted to the Court for in camera review during the hearing. Accordingly, the Court **DENIED** the Motion to Seal.

4. CONCLUSION

The motions in limine were decided as follows:

The Court **RESERVED RULING** in Part, **DENIED** in Part, and **GRANTED** in Part, Defendant's Motion to Exclude the Testimony of Mark Gallagher, Doc. 220.

The Court **DENIED** Plaintiff's Motion in Limine #1, Doc. 226.

The Court **RESERVED RULING** on Plaintiff's Motion in Limine #2, Doc. 228.

The Court **RESERVED RULING** on Plaintiff's Motion in Limine #3, Doc. 230.

The Court **RESERVED RULING** on Plaintiff's Motions in Limine #4, Doc. 232.

The Court **DENIED** Plaintiff's Motion in Limine #5, Doc. 234.

The Court **DENIED** Plaintiff's Motion in Limine #6, Doc. 237.

The Court **DENIED** Plaintiff's Motion in Limine #7, Doc. 240.

The Court **RESERVED RULING** in Part, **DENIED** in Part, and **GRANTED** in Part,
Defendant's Consolidated Motions in Limine, Doc. 243.

The Court **DENIED** Defendant's Motion to Seal the Hearing, Doc. 283.

The Clerk is **REQUESTED** to deliver a copy of this Order to all counsel of record.

It is so **ORDERED**.

/s/

Henry Coke Morgan, Jr.

~~Senior United States District Judge~~

HENRY COKE MORGAN, JR.

SENIOR UNITED STATES DISTRICT JUDGE

Norfolk, VA

Date: October 31, 2014